



New Requirements for the Hospital Outpatient Prospective Payment System (OPPS) Drug and Biological Pass-Through Application

Background:

Section 1833(t)(6) of the Act provides for temporary additional payments or “transitional pass-through payments” for certain drugs and biological agents. As originally enacted by the BBRA, this provision required the Secretary to make additional payments to hospitals for: current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act (Pub. L. 107-186); current drugs and biological agents and brachytherapy used for the treatment of cancer; and current radiopharmaceutical drugs and biological products. For those drugs and biological agents referred to as “current,” the transitional pass-through payment began on the first date the hospital OPPS was implemented (before enactment of BIPA (Pub. L. 106-554), on December 21, 2000).

Transitional pass-through payments are also provided for certain “new” drugs, devices and biological agents that were not being paid for as a hospital outpatient department service as of December 31, 1996, and whose cost is “not insignificant” in relation to the OPPS payment for the procedures or services associated with the new drug, device, or biological. Under the statute, transitional pass-through payments can be made for at least 2 years but not more than 3 years.

In the application to request transitional pass-through payment for drugs and biologicals, CMS currently requires the submission of a copy of the United States Pharmacopeia (USP) Monograph (or a letter stating that the product has been approved for inclusion in the USP) for non-implantable biologicals if the product has not received FDA approval as a biologic. This requirement ensures that non-implantable biologicals that have not received FDA approval as a biologic conform to the definition of a drug or biological as provided in the statute at section 1861(t)(1):

The term “drugs” and the term “biologicals”, except for purposes of subsection (m)(5) and paragraph (2), include only such drugs (including contrast agents) and biologicals, respectively, as are included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary, or the United States Homeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein), or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital.

Drug and Biological Pass-Through Application Policy Revision:

Section 1861(t)(1) of the Social Security Act requires inclusion in the USP (or other publication listed above) or hospital pharmacy and therapeutics (P&T) committee approval. Based on this section of the Act, we believe that the supporting information necessary to indicate that a non-implantable biological conforms to the definition of a drug or biological under 1861(t)(1) may include either a copy of the USP monograph (or a letter stating that the product has been approved for inclusion in the USP) or letters from hospitals indicating P&T committee approval.

Therefore, we are revising our list of pass-through application requirements such that applicants will be required to submit a copy of the USP monograph (or a letter stating that the product has been approved

for inclusion in the USP) for the product or letters from unrelated hospitals indicating that the product has been approved by the P&T committee (or equivalent committee) of the medical staff of certain hospitals furnishing the non-implantable biological product for use in these hospitals. Specifically, for the latter option, we will require one letter from a hospital located within each of the 12 Medicare Administrative Contractor (MAC) jurisdictions, for a total of 12 letters.

This policy revision takes effect for applications to request transitional pass-through status effective January 1, 2015. For the three remaining pass-through application opportunities in calendar year 2014 (with pass-through status effective dates of April 1, July 1, and October 1), we are implementing an interim policy with regard to the submission of hospital letters. Instead of the 12 letters referred to above, the interim policy requires the submission of one letter from three unrelated hospitals, for a total of three letters. This policy change will be reflected in item # 11 of the OPPS drug and biological pass-through application that is located at the following link: http://cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html